PathNotes User Manual

Colorectal Cancer

Based upon ICCR version 1.0 published in April 2020 and
RCPA version 4.2 published in November 2020

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User Instructions for Colorectal Cancer Structured Report

Program is based upon the ICCR Colorectal Cancer version 1.0 published in April 2020 and the RCPA Colorectal Cancer version 4.2 published in November 2020.

The aim of the program is to provide pathologists with a simple, straightforward and time effective way to produce a structured report that complies with RCPA/ICCR protocols.

The following is a step by step guide to using the PathNotes software. Welcome and thank you for choosing PathNotes.

RCPA Colorectal Structured Report

Based on ICCR Structured Report v1.0 April 2020

* - Standard items

DEMOGRAPHICS ☑

* CLINICAL INFORMATION ☐
- ☐ Information not provided
- ☐ Known polyposis syndrome
- ☐ Lynch syndrome
- ☐ Chronic inflammatory bowel disease
- ☐ Previous polyp(s)
- ☐ Previous colorectal cancer
- ☐ Other (specify)

OTHER CLINICAL COMMENT(S)

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⊞ ∨   ↺   ↻   Paragraph   ∨   **B**   *I*   ≔ ∨   ☰ ∨   ☰   ☰   ☰   ☰

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* NEOADJUVANT THERAPY
- ☐ Information not provided
- ○ Not administered
- ○ Administered (describe)

* OPERATIVE PROCEDURE:
- ○ Total colectomy
- ○ Proctocolectomy
- ○ Right hemicolectomy
- ○ Extended right hemicolectomy
- ○ Transverse colectomy
- ○ Left hemicolectomy
- ○ Sigmoid colectomy
- ○ Anterior resection
- ○ High anterior resection
- ○ Low anterior resection
- ○ Hartmann's procedure
- ○ Abdominoperineal resection
- ○ Other

It is important to note the conventions using in these programs:
- radio button indicates only one selection can be chosen
- checkboxes often indicate that more than one selection can be chosen
- Textboxes permit text (note: some will only permit numbers to be entered if the field required is numeric ie. millimetres, percentage)
- The majority of the sections/headings are hyperlinks (website links) to further information provided by either the ICCR or RCPA

The premise of this program is to only prompt the reporting Pathologist with relevant fields and hide irrelevant sections for reporting. Therefore, the complexity of the program will change depending upon the complexity of the specimen.

As per the ICCR and RCPA protocols, CORE elements are denoted with a * (red asterisk) in the heading/title. This means that the reporting pathologist is required to complete this section for the report. If it is not answered, a 'NOT STATED' will appear in the report. NON-CORE elements do not have an asterisk next to the title and if they are not reported/left blank, they are not referenced in the final report ('NOT STATED' will not appear in the report).

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Demographics

RCPA protocol

The demographics is a section that is optional. This is a requirement on each RCPA structured reporting protocols.

Upon opening the protocol, you will see the section has already been selected (ticked). This option is used to HIDE the features. If this remains checked, no demographics section will appear on the report.

To open the demographics section, uncheck the checkbox and it will appear.

Enter in the data. If a field has been missed, it will be reported as 'NOT STATED' in the report.

Ethnicity

Four options are available for Ethnicity in the RCPA protocol

Ethnicity:	○ Unknown
	○ Aboriginal/Torres Strait Islander (AU)
	○ Maori
	○ Other ethnicity

If 'Other ethnicity' is selected, then a Textbox is revealed for the pathologist to input the data

Ethnicity:	○ Unknown	
	○ Aboriginal/Torres Strait Islander (AU)	
	○ Maori	
	● Other ethnicity	please state

Clinical information

This is a NON-CORE element.

This section is to provide the background for the patient/specimen.

If either the 'Information not provided' or 'Clinical' (checkbox at the top) is selected, the options below will be hidden and unchecked with any text in the 'Other' field removed.

The Clinical information selection reveal the following options:

Neoadjuvant therapy

This is a (*) CORE element.

* NEOADJUVANT THERAPY

☐ Information not provided

○ Not administered

○ Administered (describe)

Selecting the checkbox 'Information not provided' hides the remainder of the selections and unchecks any information.

Selecting 'Administered (describe)' reveals:
- Textbox that can provide formatted text in the final report
- Microscopic → **RESPONSE TO NEOADJUVANT THERAPY** (shown below)

* RESPONSE TO NEOADJUVANT THERAPY:

○ Complete response - no viable cells (score 0)

○ Near complete response - single cells or rare groups of cancer cells (score 1)

○ Partial response - residual cancer evident tumour regression (score 2)

○ Poor or no response - extensive residual cancer with no evident tumour regression (score 3)

○ Cannot be assessed

Operative Procedure

This is a (*) CORE element.

* <u>OPERATIVE PROCEDURE:</u>

- ○ Total colectomy
- ○ Proctocolectomy
- ○ Right hemicolectomy
- ○ Extended right hemicolectomy
- ○ Transverse colectomy
- ○ Left hemicolectomy
- ○ Sigmoid colectomy
- ○ Anterior resection
- ○ High anterior resection
- ○ Low anterior resection
- ○ Hartmann's procedure
- ○ Abdominoperineal resection
- ○ Other

Abdominoperineal resection

If 'Abdominoperineal resection' is selected, the following is revealed in MACROSCOPIC →
PLANE OF SPHINCTER EXCISION (as per shown below).

<u>PLANE OF SPHINCTER EXCISION:</u>

- ○ Extralevator plane
- ○ Sphincter plane
- ○ Intrasphincteric plane

Macroscopic

This section can be hidden by selecting the checkbox next to **MACROSCOPIC**.

When this checkbox is selected (as per above) in the **MACROSCOPIC** section, all information contained within is erased and reset.

Specimen labelled

This is a (*) CORE element.

This is a free text field.

Specimen length

This is a (*) CORE element.

* SPECIMEN LENGTH: `mm`

This is a textbox restricted to numbers with a 5 digit limit with 'mm' added to the end of the text in the report.

Tumour site

This is a (*) CORE element.

* TUMOUR SITE:

- ☐ Not specified
- ☐ Caecum
- ☐ Ascending colon
- ☐ Hepatic flexure
- ☐ Transverse colon
- ☐ Splenic flexure
- ☐ Descending colon
- ☐ Sigmoid colon
- ☐ Rectosigmoid
- ☐ Rectum
- ☐ Other

Multiple sites can be selected. If 'Not specified' is selected, the remainder of the options are hidden and reset.

Plane of Mesocolic Excision

If any anatomical structures from the 'Caecum' to the 'Sigmoid colon' are selected, the **PLANE OF MESOCOLIC EXCISION** is revealed.

PLANE OF MESOCOLIC EXCISION:

○ Mesocolic plane

○ Intramesocolic plane

○ Muscularis propria plane

Rectum

If 'Rectum' is selected, the following elements are revealed:
- Relation of tumour to Anterior Peritoneal Reflection and
- Plane of Mesorectal excision.

Relation of tumour to Anterior Peritoneal Reflection

☑ Rectum

* **RELATION OF TUMOUR TO ANTERIOR PERITONEAL REFLECTION:**

○ Entirely above

○ Astride

○ Entirely below

Plane of Mesorectal excision

* **PLANE OF MESORECTAL EXCISION:**

○ Mesorectal fascia (complete)

○ Intramesorectal (near complete)

○ Muscularis propria (incomplete)

Tumour Dimension

This is a (*) CORE element.

Two free textbox fields are present:
- Maximum tumour dimension and
- Additional dimensions (optional)

* TUMOUR DIMENSIONS:

Cannot be assessed ☐

Maximum tumour dimension: [   ] mm

Additional dimensions (optional): [   ] mm

It is free text to provide flexibility of the input to be either a single entry (ie. 12) or provide dimensions (ie. 12x5x7). Both fields have 'mm' inserted at the end of the text in the report (user not required to put this in).

Selecting the 'Cannot be assessed' checkbox hides both textboxes below and resets any values within.

Distance of tumour to the nearer proximal or distal 'cut end'

This is a NON-CORE element.

This is a RCPA only requirement.

DISTANCE OF TUMOUR TO NEARER PROXIMAL OR DISTAL 'CUT END': [mm (leave blank if N/A)]

If this is not relevant, leave blank and it will not appear in the final report.

Distance of tumour to the non-peritonealised circumferential margin

This is a NON-CORE element.

This is a RCPA only requirement.

DISTANCE OF TUMOUR TO THE NONPERITONEALISED CIRCUMFERENTIAL MARGIN: [mm (leave blank if N/A)]

If this is not relevant, leave blank and it will not appear in the final report.

Perforation

This is a (*) CORE element.

* PERFORATION: ^c

◯ Not identified

◯ Present

^c*Defined as a macroscopically visible full thickness defect in the wall*

If 'Present' is selected, the following is revealed:

* PERFORATION: ^c

◯ Not identified

◉ Present

    ◯ Through tumour (tumour perforation)

    ◯ Not involving tumour

^c*Defined as a macroscopically visible full thickness defect in the wall*

Peritoneum

This is a NON-CORE element.

PERITONEUM:

◯ No peritoneal involvement

◯ Tumour invades to the peritoneal surface

◯ Tumour has formed nodule(s) discrete from the tumour mass along the serosal surface

Other Macroscopic Comments and Block Designation

These are NON-CORE elements.

Both are able to contain formatted text.

If left blank, these fields will not be entered into the report.

Microscopic Description

The microscopic description includes:
- Histological tumour type (*)
- Histological tumour grade (*)
- Extent of invasion (*)
- Inflammatory cell infiltrate
- Measurement of invasion beyond muscularis propria
- Lymphatic and venous invasion (*)
- Perineural invasion
- Lymph nodes status (*)
- Apical node involvement
- Tumour deposits (*)
- Tumour budding
- Response to neoadjuvant therapy (*)
- Margin status (*)
- Coexistent Pathology
- Additional Microscopic Description & Comments

MICROSCOPIC ☐

* HISTOLOGICAL TUMOUR TYPE:

- ○ No evidence of residual tumour
- ○ Adenocarcinoma (NOS)
- ○ Mucinous adenocarcinoma
- ○ Signet-ring cell carcinoma
- ○ Medullary carcinoma
- ○ Serrated adenocarcinoma
- ○ Micropapillary carcinoma
- ○ Adenoma-like adenocarcinoma
- ○ Neuroendocrine carcinoma
- ○ Mixed neuroendocrine-non-neuroendocrine neoplasm (MiNEN)
- ○ Other (specify)

* EXTENT OF INVASION:

- ○ Cannot be assessed
- ○ No evidence of primary tumour
- ○ High grade dysplasia/non-invasive neoplasia
- ○ Tumour invades submucosa
- ○ Tumour invades muscularis propria
- ○ Invasion into the subserosa or into pericolic or perirectal connective tissues
- ○ Invasion onto the surface of the visceral peritoneum
- ○ Invasion directly into other structures/organs (specify)

INFLAMMATORY CELL INFILTRATE: [Record scoring system used (blank if NA)]

* LYMPHATIC AND VENOUS INVASION

- ○ Not identified
- ○ Present

* PERINEURAL INVASION

- ○ Not identified
- ○ Present

* LYMPH NODE STATUS:

- ○ Cannot be assessed
- ○ No nodes submitted or found
- ○ Not involved
- ○ Involved

Note: the reporting Pathologist is able to hide the microscopic description segment. This means none of the fields contained in this section will be reported. If this checkbox is selected, all elements (including any information that has been selected/written) will be reset to the default/unchecked values.

MICROSCOPY ☑

Histological tumour type

This is a (*) CORE element.

HISTOLOGICAL TUMOUR TYPE:

○ No evidence of residual tumour

○ Adenocarcinoma (NOS)

○ Mucinous adenocarcinoma

○ Signet-ring cell carcinoma

○ Medullary carcinoma

○ Serrated adenocarcinoma

○ Micropapillary carcinoma

○ Adenoma-like adenocarcinoma

○ Neuroendocrine carcinoma

○ Mixed neuroendocrine-non-neuroendocrine neoplasm (MiNEN)

○ Other (specify)

One selection is able to be made.

Neuroendocrine

If 'Neuroendocrine carcinoma' is selected:

◉ Neuroendocrine carcinoma

    ○ Small cell type

    ○ Large cell type

Histological tumour grade

This is a (*) CORE element.

This element is revealed when the following selections are made in the **HISTOLOGICAL TUMOUR TYPE**:
- Adenocarcinoma (NOS)
- Mucinous adenocarcinoma

It shows:

* **HISTOLOGICAL TUMOUR GRADE:**

○ Not applicable

○ Low grade (formerly well to moderately differentiated)

○ High grade (formerly poorly differentiated)

Extent of invasion

This is a (*) CORE element.

* **EXTENT OF INVASION:**

○ Cannot be assessed

○ No evidence of primary tumour

○ High grade dysplasia/non-invasive neoplasia

○ Tumour invades submucosa

○ Tumour invades muscularis propria

○ Invasion into the subserosa or into pericolic or perirectal connective tissues

○ Invasion onto the surface of the visceral peritoneum

○ Invasion directly into other structures/organs (specify)

Measurement of invasion beyond muscularis propria

This is a NON-CORE element.

This is revealed when a pT3 tumour (ie 'Invasion into the subserosa or into pericolic or perirectal connective tissue') from **EXTENT OF INVASION** is selected:

MEASUREMENT OF INVASION BEYOND MUSCLARIS PROPRIA:

Cannot be assessed ☐

Distance of invasion beyond the muscularis propria (nearest 1mm): [   ] mm

Only numbers can be used in the textbox. This is limited to 2 digits only.

If 'Cannot be assessed' is selected, any text in the textbox is removed.

Inflammatory cell infiltrate

This is a NON-CORE element.

This is only from the RCPA protocol.

INFLAMMATORY CELL INFILTRATE: [Record scoring system used (blank if NA)]

Lymphatic and venous invasion

This is a (*) CORE element.

* **LYMPHATIC AND VENOUS INVASION**

○ Not identified

○ Present

If 'Present' is selected:

○ Not identified

◉ Present

　☐ Small vessel (lymphatic, capillary or venular)

　☐ Large vessel (venous)

If 'Large vessel (venous)' is selected:

○ Not identified

◉ Present

    ☐ Small vessel (lymphatic, capillary or venular)

    ☑ Large vessel (venous)

        ☐ Intramural

        ☐ Extramural

Selecting 'Not idenfied' will hide and reset values under 'Present' if they have been previously selected.

Perineural invasion

This is a (*) CORE element.

* PERINEURAL INVASION

○ Not identified

○ Present

Lymph node status

This is a (*) CORE element.

* LYMPH NODE STATUS:

○ Cannot be assessed

○ No nodes submitted or found

○ Not involved

○ Involved

If 'Not involved' is selected, a textbox appears below to input the number of lymph nodes found.

* LYMPH NODE STATUS:

○ Cannot be assessed

○ No nodes submitted or found

◉ Not involved

○ Involved

> Total nodes

This textbox only permits numbers and has a 2 digit limit.

If 'Involved' is selected, two textboxes appear below:

* LYMPH NODE STATUS:

○ Cannot be assessed

○ No nodes submitted or found

○ Not involved

◉ Involved

> Involved nodes   /   Total nodes

Both textboxes only permit numbers and are both limited to 2 digits.

Apical node involvement

This is a NON-CORE element.

This is only from the RCPA protocol.

APICAL NODE INVOLVEMENT

○ Not applicable

○ Absent

○ Present

If 'Not applicable' is selected, then it will not appear in the report.

Tumour deposits

This is a (*) CORE element.

> *** TUMOUR DEPOSITS**
>
> ○ Not identified
>
> ○ Present

If 'Present' is selected:

> *** TUMOUR DEPOSITS**
>
> ○ Not identified
>
> ⦿ Present
>
>   ○ Vascular
>
>   ○ Other
>
>   Number of tumour deposits: [specify no.]

The radio buttons for 'Vascular' and 'Other' are from the RCPA protocol only. If left blank, then they are not reported.

The textbox permits only numbers to be entered in and only permits 2 digits.

Tumour budding

This is a NON-CORE element.

When a non-mucinous or non-signet ring cell adenocarcinoma is selected in the **HISTOLOGICAL TUMOUR TYPE**, Tumour budding secion appears:

> **TUMOUR BUDDING:**
>
> Cannot be assessed ☐
>
> Number of tumour buds: [specify no.]
>
>   **Tumour budding score**
>
>   ○ Bd1 - low budding (0-4 buds)
>
>   ○ Bd2 - intermediate budding (5-9 buds)
>
>   ○ Bd3 - high budding (> or = 10 buds)

The textbox permits only numbers to be entered in and only permits 2 digits.

If 'Cannot be assessed' is selected, the fields below are hidden and reset.

Response to neoadjuvant therapy

This is a (*) CORE element.

When 'Administered (describe)' is selected in the **NEOADJUVANT THERAPY** at the start of the program, the following section appears → **RESPONSE TO NEOADJUVANT THERAPY** (shown below):

* RESPONSE TO NEOADJUVANT THERAPY:
- ○ Complete response - no viable cells (score 0)
- ○ Near complete response - single cells or rare groups of cancer cells (score 1)
- ○ Partial response - residual cancer evident tumour regression (score 2)
- ○ Poor or no response - extensive residual cancer with no evident tumour regression (score 3)
- ○ Cannot be assessed

If 'Cannot be assessed' is selected, a textbox is revealed for further information.

Coexisting pathology

This is a NON-CORE element.

COEXISTING PATHOLOGY:
- ☐ None identified
- ☐ Polyp(s)
- ☐ Synchronous carcinoma
- ☐ Other (specify)

If 'Polyp', 'Synchronous carcinoma' or 'Other' are selected, textboxes appear for further information.

If ' None identified' is selected, the remaining options are hidden and reset.

Margin status

This is a (*) CORE element.

* MARGIN STATUS:

Longitudinal margin status:

- ○ Cannot be assessed
- ○ Not involved
- ○ Involved

Circumferential margin status:

- ○ Cannot be assessed
- ○ Not involved
- ○ Involved (≤1 mm)

Longitudinal margin status

If 'Not involved' is selected:

Longitudinal margin status:

- ○ Cannot be assessed
- ◉ Not involved

  Estimate distance to closer margin: | specify | mm

- ○ Involved

The textbox permits only numbers to be entered and is limited to 5 digits.

If 'Involved' is selected:

Longitudinal margin status:

- ○ Cannot be assessed
- ○ Not involved
- ◉ Involved

  Details (specify): | Proximal or distal margin |

Circumferential margin status

If 'Not involved' is selected:

Circumferential margin status:

○ Cannot be assessed

◉ Not involved

  Distal margin (≥10 mm) ☐

  Clearance (specify if <10 mm): [specify to 0.1mm] mm

○ Involved (≤1 mm)

If 'Distal margin ≥ 10mm)' is selected, the textbox below it is hidden and reset.

The textbox permits only numbers to be entered and is limited to 5 digits.

If 'Involved' is selected:

Circumferential margin status:

○ Cannot be assessed

○ Not involved

◉ Involved (≤1 mm)

  Distance (specify): [specify 0mm or distance to nearest 0.1mm] mm

    ○ By primary tumour

    ○ By other (specify)

If 'By other (specify)' is selected, a textbox is revealed for further details.

Distant metastases

This is a (*) CORE element.

* DISTANT METASTASES

   ◯   Not identified

   ◯   Present

If 'Present' is selected:

* DISTANT METASTASES

   ◯   Not identified

   ◉   Present

   Specify site(s):   free text

Microscopic residual tumour status

This is a NON-CORE element.

When 'Administered (describe)' is selected in the **NEOADJUVANT THERAPY** at the start of the program, the following section appears → **MICROSCOPIC RESIDUAL TUMOUR STATUS** (shown below):

* MICROSCOPIC RESIDUAL TUMOUR STATUS: please state

Additional microscopic description and Comments

This is a NON-CORE element.

Formatted text is permitted in these textboxes.

ADDITIONAL MICROSCOPIC DESCRIPTION (optional)

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COMMENT(S) (optional)

File   Edit   View   Insert   Format   Table

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Ancillary studies

This is a NON-CORE element.

If the checkbox next to **ANCILLARY STUDIES** is selected, the entire section is hidden and reset.

Mismatch repair (MMR) immunohistochemistry

If 'MMR Deficient' is selected:

Mismatch repair (MMR) immunohistochemistry:

○ Not tested

○ Not interpretable

○ MMR Proficient

◉ MMR Deficient

    ○ MLH1/PMS2 loss

    ○ MSH2/MSH6 loss

    ○ MSH6 loss

    ○ PMS2 loss

    Other (specify) [optional]

Pathological staging

This is a (*) CORE element.

The checkboxes for 'm – multiple primary tumours', 'r – recurrent', and 'y – post-therapy' are all optional. If left blank, they will not appear on the report.

The Tumour, Nodes, Metastasis, and Stage are required. If they are not selected, then 'NOT STATED' will appear on the report.

If the checkbox next the **STAGING** is selected (at the top of the section), the section will be hidden and not reported.

Diagnostic summary

This is an additional feature for the reporting Pathologist to consider adding to the report:
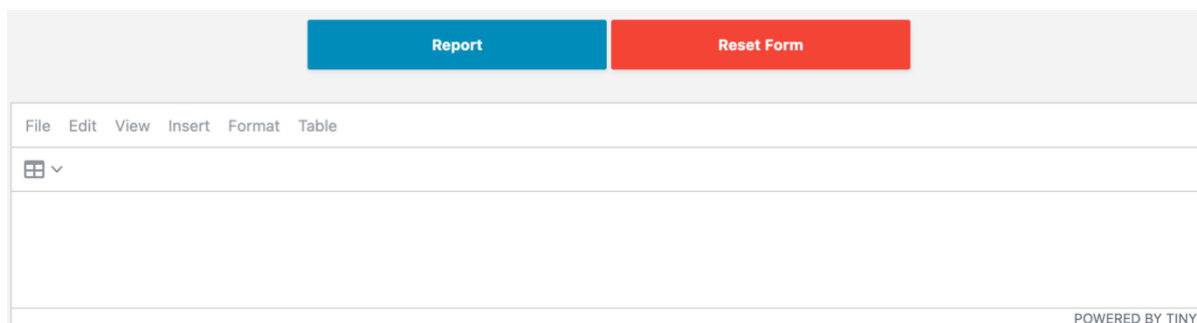
DIAGNOSTIC SUMMARY:
- ● None (default)
- ○ At the top of report
- ○ At the end of report

This will provide an Executive summary or Diagnostic summary of the report either at the top or end of the report.

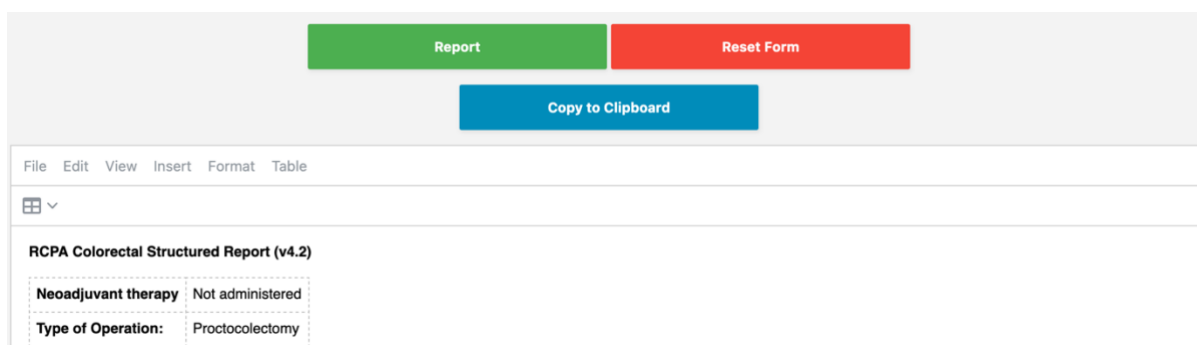If one is not required, leave it as 'None'.

Generating the report

At the end of the page is two buttons:

Once the reporting Pathologist has entered in all of the data, pressing the 'Report' button will generate the report in the textbox underneath:
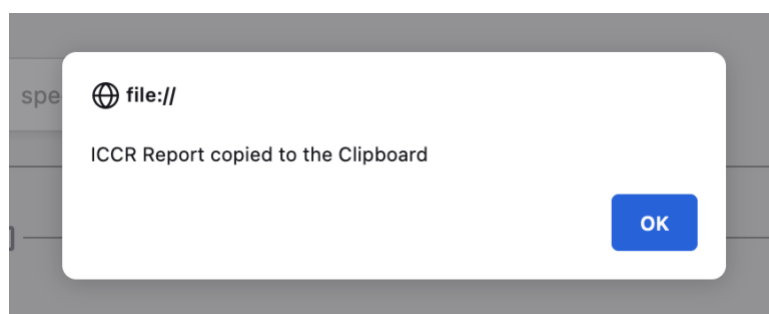

This will also reveal a 'Copy to Clipboard' button.

Once the reporting Pathologist has confirmed the information in the generated report is accurate, the 'Copy to Clipboard' can be selected.

The reporting Pathologist can then copy this into any program (ie Microscoft Word, Notepad etc..) and the structured report will be inserted.